

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 6-15 and 20-30 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. New claim 30 is based on the limitations of claims 6 and 12-14, as well as the preferred embodiment described at page 6, lines 13-20, of the specification.

35 U.S.C. 103 – Nonobviousness

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing the legal standard provided in *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See id. ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). The use of hindsight reasoning is impermissible. See id. at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning"). Thus, a *prima facie* case of obviousness under Section 103(a) requires "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." *Kahn*, 78 USPQ2d at 1335; see *KSR*, 82 USPQ2d at 1396. A claim which is directed to a combination of prior art elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Id. at 1396. Finally, a determination of *prima facie* obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 6, 8-13 and 20-29 were rejected under Section 103(a) as allegedly unpatentable over Tanekawa et al. (U.S. Patent 4,303,680), as evidenced by Kanegae et al. (U.S. Patent 4,810,509) and Chae et al. (Bioresource Technol. 76:253-258, 2001) in view of Keller et al. (U.S. Patent 4,623,723). Applicants traverse.

The cell extract made according to Tanekawa contains 5'-nucleotides in addition to free amino acids and oligopeptides. The cited documents neither teach nor suggest "separating the RNA present in the released cell contents from other soluble cell material" as required by Applicants' claims, or a reasonable expectation of success that their combined disclosures would result in Applicant's claimed invention. Keller discloses a filter separation process in which RNA passes to the permeate while DNA remains in the retentate. All of the soluble material in the cell extract having a smaller or the same size as the RNA (e.g., free amino acids and short oligopeptides) also passes through the membrane into the filtrate. Thus, neither Tanekawa nor Keller separates RNA from other soluble cell material (e.g., free amino acids and short oligopeptides). In contrast to the situation in Keller where the RNA is in the permeate, Applicants' RNA is found in the retentate when ultrafiltration is used (page 6, lines 16-17, of the specification).

Note that there appears to be a typographical error (i.e., at least 75% w/w of 5'-ribonucleotides should be at least 55% w/w of 5'-ribonucleotides) at page 6, line 12, of the Office Action since claim 20 is cited by the Examiner.

In the alternative, the cited documents do not teach or suggest "a composition that is 100% 5'-ribonucleotides" as alleged on page 7, line 4, of the Office Action. Col. 2, lines 45-49, of Keller only discloses precipitating RNA from the permeate. RNA are poly-ribonucleotides; 5'-ribonucleotides are monoribonucleotides. There is no evidence that the hydrolysis products of RNA (such as 5'-ribonucleotides) or their concentration (if it is assumed that hydrolysis products are present) is known for the purified composition disclosed in Keller. To emphasize this point, claim 20 is reformatted as an independent claim and amended to incorporate the limitations of independent claim 6.

Claims 6-7 and 25 were rejected under Section 103(a) as allegedly unpatentable over Tanekawa et al. in view of Keller et al., and further in view of Potman et al. (U.S. Patent 5,288,509). Applicants traverse.

The failure of Tanekawa and Keller to disclose the invention of claim 6 is not remedied by the attempt to combine that disclosure with Potman. As discussed above, Tanekawa and Keller do not render obvious the claimed invention. Potman was cited as allegedly disclosing deactivation of native enzymes prior to enzymatic degradation of cells with a protease (see page 9 of the Action). Even if assumed true for the sake of argument, this disclosure of Potman does not address the failure of the cited documents to teach or suggest separating RNA from other soluble cell material OR a particular concentration of 5'-ribonucleotides. Applicants submit that these features of their claimed invention are sufficient to distinguish over the cited documents so any other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Therefore, the combination of Tanekawa, Keller, and Potman does not render obvious the claimed invention because all limitations of claim 6 are not fairly taught or suggested by the cited documents. Moreover, claims depending from that independent claims are also not made obvious by the documents because limitations of claim 6 are incorporated in the dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 6 and 14-15 were rejected under Section 103(a) as allegedly unpatentable over Tanekawa et al. in view of Keller et al., and further in view of Tsuda et al. (U.S. Patent 4,374,981). Applicants traverse.

The failure of Tanekawa and Keller to disclose the invention of claim 6 is not remedied by the attempt to combine that disclosure with Tsuda. As discussed above, Tanekawa and Keller do not render obvious the claimed invention. Tsuda was cited as allegedly disclosing separation of inosine and/or guanosine by ultrafiltration to remove high molecular weight substances (see page 10 of the Action). Even if assumed true for the sake of argument, this disclosure of Tsuda does not remedy the failure of the cited documents to teach or suggest separating RNA from other soluble cell material OR a particular concentration of 5'-ribonucleotides. Applicants submit that these features of their claimed invention are sufficient to distinguish over the cited documents so any

other incorrect allegations about their disclosures are not disputed here, but the opportunity to dispute them in the future is reserved.

Therefore, the combination of Tanekawa, Keller, and Tsuda does not render obvious the claimed invention because all limitations of claim 6 are not fairly taught or suggested by the cited documents. Moreover, claims depending from that independent claims are also not made obvious by the documents because limitations of claim 6 are incorporated in the dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Withdrawal of the Section 103 rejections is requested because the claims would not have been obvious to one of ordinarily skill in the art when this invention was made.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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